Prepared for:

The Office of the National Coordinator for Health Information Technology



An Open Source Meaningful Use Stage 2 Clinical Quality Measure Testing and Certification Tool

V2.4 User Guide

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Table of Contents

Target Audience	5
Cypress Testing Capabilities	5
1. Capture and Export	5
Figure 1: Capture and Export	7
2. Import and Calculate	7
3. Electronic Submission	7
Figure 2: Import, Calculate and Electronic Submission	8
Testing Procedure Overview	9
Figure 3: Authorized Testing Lab Workflow Illustration	9
User Guide Detailed Description	10
Accessing Cypress	10
Figure 4: Cypress Login in	10
Figure 5: Cypress Account and Terms and Conditions	11
Figure 6: Cypress Account Creation	12
Cypress Administrative Functions	13
Figure 7: Certification Dashboard No Vendors Added	13
Figure 8: Account Password Update	14
Figure 9: Cypress Feedback Mechanisms	14
Figure 10: Cypress v2.4 Logout	15
Master Patient List	16
Figure 11: Master Patient List of Test Patients	16
Figure 12: Patients Specific to CMS26v1 NQF:0338	16
Figure 13: Patient Test Record Data Requirements and CQM Qualifiers	17
Figure 14: Download Options Menu	17
Cypress v2.4 Preparation for Testing	18
Figure 15: Certification Dashboard Select Add EHR Vendor	18
Figure 16: Vendor and Contact Form	18
Figure 17: Vendor Certification Dashboard with no products added	19
Figure 18: Vendor Certification Dashboard Product List	19
Figure 19: EHR Product Form	20
Figure 20: Certification Dashboard showing a vendor with one product added	20
Product Test Creation	21
Figure 21:Dashboard showing Product and No Tests Added	21
Figure 22: Create New Test Step 1 Basic Information	21
Figure 23: Create New Test – Step 2 CQM Selection	22

Figure 24: New Test Created	22
Test Execution	23
Figure 25: Select New Test	23
Download Patient Data	24
Figure 26: Download Patient Data for Import	24
Figure 27: Listing of Zip File HTML Patient Test Data CQMs to be tested	24
Figure 28: HTML for one Patient Record	25
Upload Results for Test	26
Figure 29: Upload test execution results	26
Figure 30: Test execution with validation errors	26
Figure 31: Details of test execution with errors	27
Figure 32: Generated Category 1 Test	28
Figure 33: Download Data Cat 1 Test	28
Figure 34: Upload Category 1 Results	29
Figure 35: Category 1 Test Results	29
Test Execution Notes	30
Submit	31
Verify	
	22
cronyms	33

Target Audience

Cypress v2.4 is the rigorous and repeatable testing tool of Electronic Health Records (EHRs) and EHR modules in calculating Meaningful Use (MU) Stage 2 Clinical Quality Measures (CQMs). Cypress v2 serves as the official testing tool for the 2014 EHR Certification program supported by the Office of the National Coordinator for Health IT (ONC).

The Cypress v2.4 User Guide has been developed for use by test proctors supporting the Meaningful Use Stage 2 program to test and certify Electronic Health Record (EHR) systems at Authorized Testing Labs (ATLs). The Cypress v2.4 User Guide may also be used by EHR software engineers, quality assurance engineers, and production release engineers who wish to use Cypress in a pre---testing mode to understand how their EHR product will perform when an ATL performs an operational test with their respective EHR product.

The Cypress v2.4 User Guide provides instructions on how to use the Cypress Testing Tool Software. This Cypress v2.4 User Guide assumes you have downloaded the Cypress v2.4 open source software and discusses the requirements and steps for testing Electronic Health Record (EHR) technology for the calculation and reporting of Clinical Quality Measures (CQM).

The Cypress tool is open source and freely available for use or adoption by the health IT community including EHR vendors and testing labs. Information detailing the setup and configuration of Cypress v2.4 open source software is available via the open source project website http://projectcypress.org.

Cypress Testing Capabilities

The Cypress v2.4 software verifies three required clinical quality measure (CQM) capabilities for EHR certification. These include:

1. Capture and Export

Capture — EHR technology seeking certification must be able to electronically record all of the data identified in the specified procedure, §170.314(c), that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."

Export--- EHR technology must be able to electronically export a data file formatted in accordance with the Quality Reporting Document Architecture (QRDA) Category I standard that includes all of the data captured for each and every CQM to which EHR technology is being certified.

The basic concept for Capture and Export is shown below in Figure 1. The primary purpose of this step is the verification of the EHR technology's ability to export data in the proper QRDA Category 1 format, and with the proper Quality Data Model (QDM) data elements.

To verify this, Cypress produces static patient data for each of the CQMs that are to be tested, and exports the relevant patients. This data is then entered into the EHR. The EHR is then commanded to export the patient test data as a set of QRDA Category I files containing the proper elements from the QDM that are required to calculate the CQMs that are being tested. These QRDA files are loaded back into Cypress where they are tested for validity (valid QRDA Category I Extensible Markup Language (XML) documents) and correctness (contain only the elements required to calculate the CQMs, and no more).

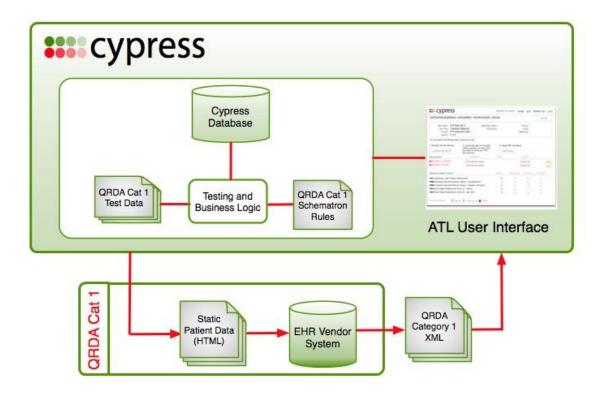


Figure 1: Capture and Export

2. Import and Calculate

Import — EHR technology must be able to electronically import a data file formatted in the QRDA Category I format.

Calculate — EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.

3. Electronic Submission

Electronic Submission — Enables a user to electronically create a data file in QRDA Category III format for transmission of clinical quality measurement data that can be electronically accepted by Centers for Medicare & Medicaid Services (CMS).

The basic concept for Import, Calculate and Electronic Submission is shown below in Figure

- 2. The purpose of these steps, is for the automated verification that an EHR system can:
 - Import and calculate the CQM results for the quality measures being certified based on the synthetic patient data that Cypress presents to the EHR system under test.

• Generate a properly formatted summary CQM report that could be electronically submitted using QRDA Category III format.

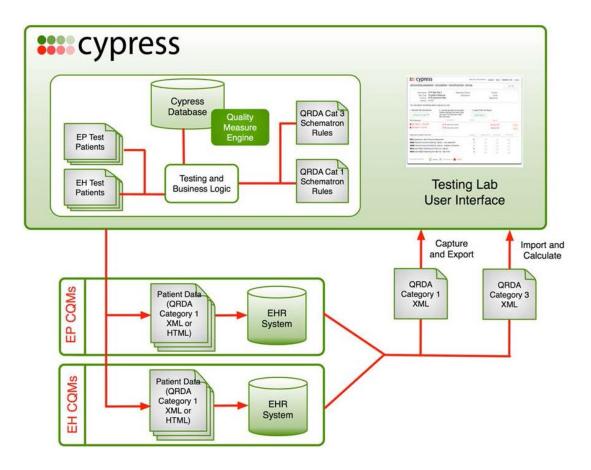


Figure 2: Import, Calculate and Electronic Submission

Testing Procedure Overview

The Figure 3 graphic below provides a general workflow of a test performed with Cypress and description of how the test procedure is organized and conducted. This test procedure is based on the ONC approved and the National Institute of Standards and Technology (NIST) published procedure augmented to include Cypress as a software tool for testing the accurate calculation, submission and degree of correctness of the CQMs.

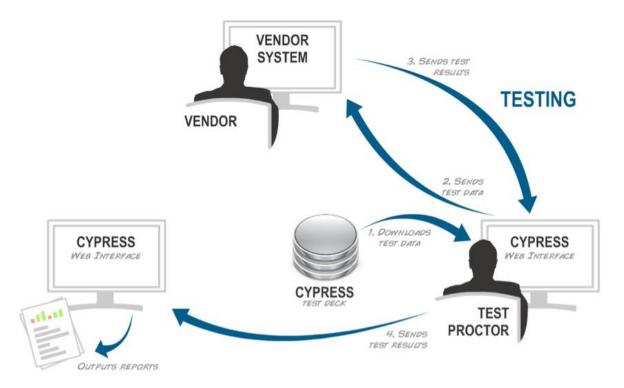


Figure 3: Authorized Testing Lab Workflow Illustration

This test procedure is centered on the open source software tool, Cypress. Cypress is capable of performing the following types of tests in support of CQM certification:

- XML Data conformance testing of the Quality Reporting Document Architecture (QRDA)
 Category 1 standard for individual patient---level data used for CQM calculation
- XML Data conformance testing of the Quality Reporting Document Architecture (QRDA) Category III standard for aggregate reporting of CQM calculation
- Accuracy calculation testing of the Meaningful Use Stage 2 Eligible Professional (EP) CQMs
- 4. Accuracy calculation testing of the Meaningful Use Stage 2 Eligible Hospital (EH) CQMs

A complete description of the Cypress Testing Procedure can be found via the Cypress website at http://projectcypress.org/resources.html.

User Guide Detailed Description

Accessing Cypress

- To access and download the Cypress Software go to http://projectcypress.org
- There are several options and detailed instructions there for downloading and installing the Cypress software. This document is not meant to provide instructions for downloading the Cypress software, so if you need to install the software, please follow the Cypress Download Instructions.

Once you have downloaded and installed the Cypress Software, you should be able to access Cypress system via a URL, bookmark or icon you have created.

- Once you access your installed instance of Cypress, the Login Screen should appear.
- To create an account, select Create new account.

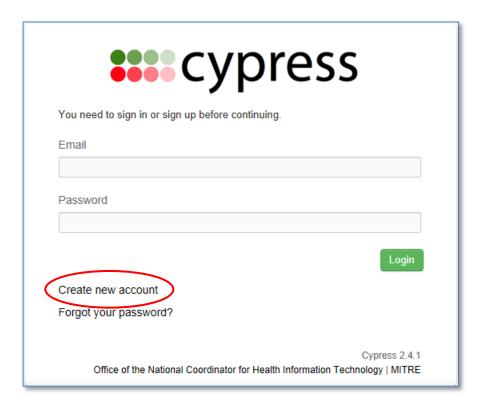


Figure 4: Cypress Login in

- If you have previously set up an account, enter your email and password and select Login.
- If you have previously created an account and forgotten your password, enter your email and select 'Forgot your Password?' And you will be sent a link to reset your password.
- Create New Account will bring you to the Account Creation and Terms and Conditions Page.

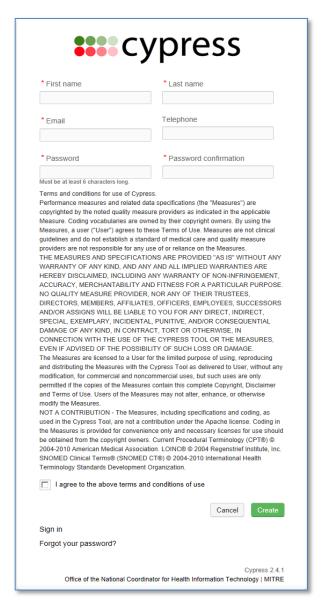


Figure 5: Cypress Account and Terms and Conditions

- To create an account, enter your First and Last Name, Email, Telephone and enter a Password and confirm your Password.
- Read the Terms and conditions and check 'Agree' and select "Create' to create your Cypress Account.

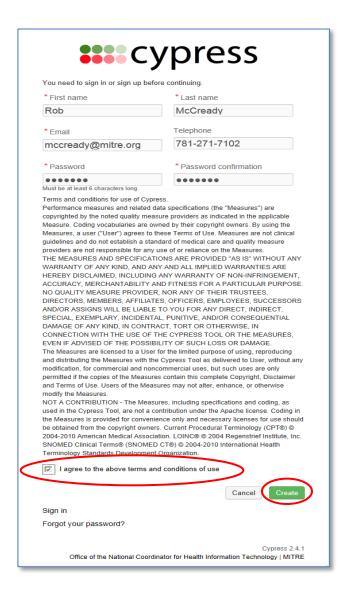


Figure 6: Cypress Account Creation

Cypress Administrative Functions Overview

• The first page displayed after your account is created is the **Certification Dashboard** and the following message is displayed:

Welcome to Cypress! This is the Certification Dashboard that displays the names of the EHR vendors and the status of their products being tested. You can begin by adding an EHR vendor or simply explore the complete Cypress Test Deck by clicking on "Master Patient List" above.

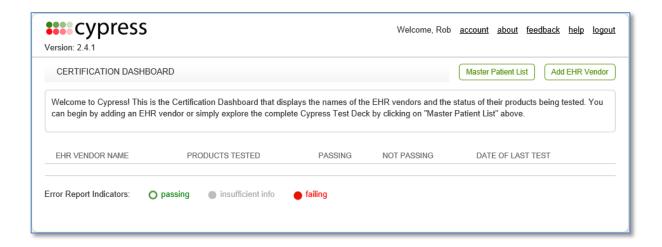


Figure 7: Certification Dashboard No Vendors Added

- The following Cypress Administrative Functions are found on the Certification Dashboard:
- 1. Account--- Update a Cypress Account Password
- 2. About--- Learn more about Cypress and review FAQs
- 3. Feedback--- Provide Feedback to the Cypress Team
- 4. Help--- Locate a Help email address, Copy of this User Guide and other resources
- 5. Logout--- Logout of the Cypress Application
- 6. Master Patient List
- 7. Add EHR Vendor

These are described in greater detail below and in the sections that follow.

Account

— If you have previously set up an account, this page will allow you to change
your Password.

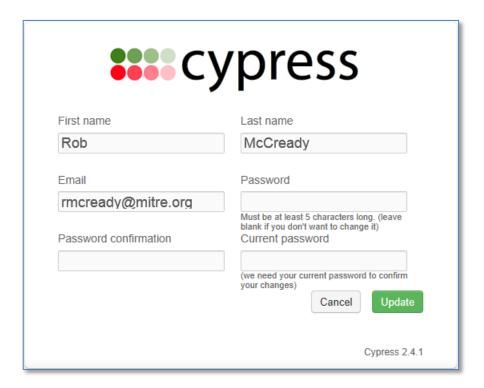


Figure 8: Account Password Update

- 2. About -- Learn more about Cypress via the publicly available project website.
- **3. Feedback** Provides several mechanisms for providing feedback on Cypress.

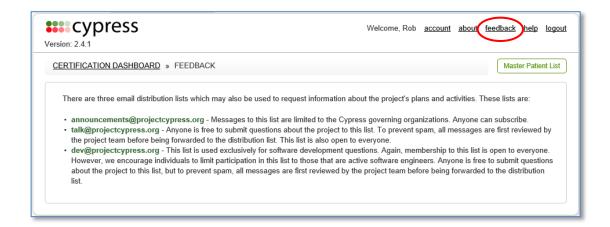


Figure 9: Cypress Feedback Mechanisms

- **4. Help** Provides help contact and additional reference information via the Cypress v2.4 Frequently Asked Questions (FAQ) page.
- **5. Logout** --- Allows you to logout of Cypress and return to the Account Sign in page.

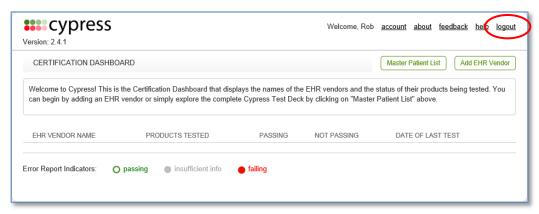


Figure 10: Cypress v2.4 Logout

- 6. Master Patient List--- Provide a list of all test data for CQMs.
 - You can select and download individual or all the patient data records.
 - You can select a record and Cypress v2.4 will display the patient test record, applicable data requirements and CQM qualifiers.
- **7. Add EHR Vendor** --- Enter EHR Vendor contact and product information (See "Prepare for Cypress 2.4 Testing" below.)

Master Patient List

• The master patient list page provides a list of all test data for CQMs and has functions for displaying or downloading this data in its entirety, or as individual patient records.

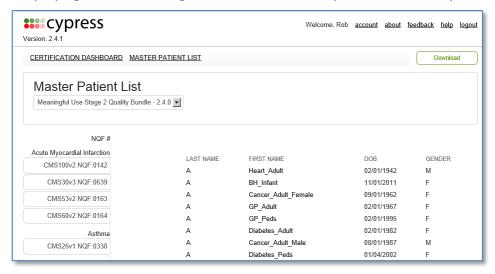


Figure 11: Master Patient List of Test Patients

 Patient records that apply to a specific CQM and CQM qualifiers can be listed by clicking on the CQM's tab.

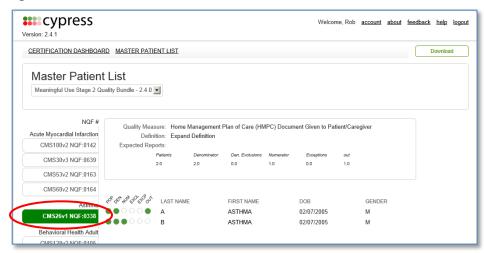


Figure 12: Patients Specific to CMS26v1 NQF:0338

 An individual patient record and their CQM qualifiers can be displayed by clicking on the patient's name in the patient record list.

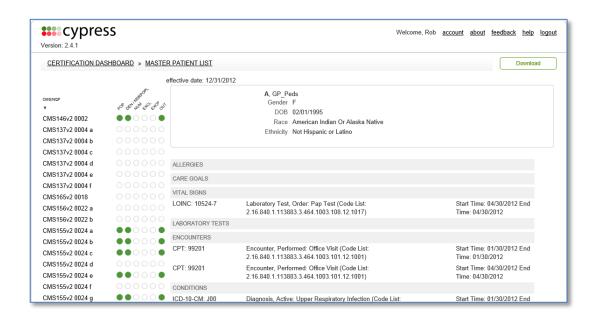


Figure 13: Patient Test Record Data Requirements and CQM Qualifiers

 Hovering the mouse over the "Download" button displays the download options menu.



Figure 14: Download Options Menu

- Patient records can be downloaded as either QRDA Cat 1 or HTML files contained in a zip archive.
- When an individual patient record is selected and displayed on the Master Patient List page, only that record is downloaded. Otherwise, all patient records in the Master Patient List will be downloaded.

Cypress v2.4 Preparation for Testing

Add Vendor Information

- Once you have created an Account, it is necessary to prepare Cypress for testing by adding a Vendor and Contact Information.
- Select Add EHR Vendor from the Certification Dashboard.

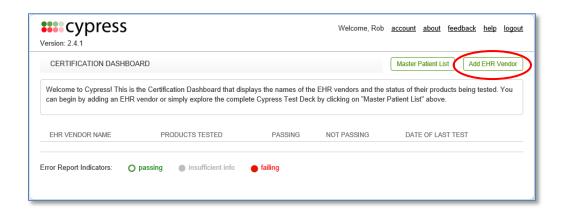


Figure 15: Certification Dashboard Select Add EHR Vendor

- The Vendor Information and Contact Form will be displayed.
- Complete the Vendor Information and Contact Form and select Create.

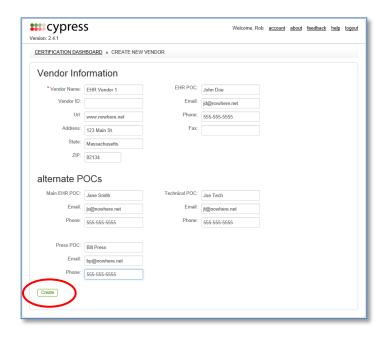


Figure 16: Vendor and Contact Form

Enter Product Information

 The next step is to enter Product Information. Begin by clicking the vendor name displayed on the Certification Dashboard.

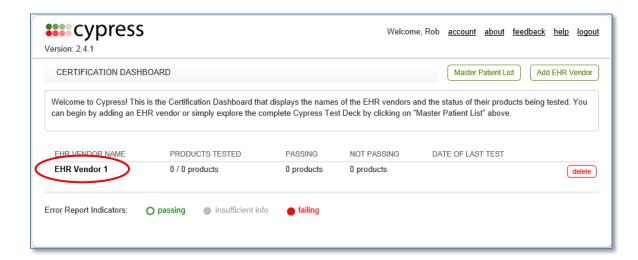


Figure 17: Vendor Certification Dashboard with no products added

 With the Vendor Product List displayed on the Certification Dashboard, click Add Product to begin entering product information.

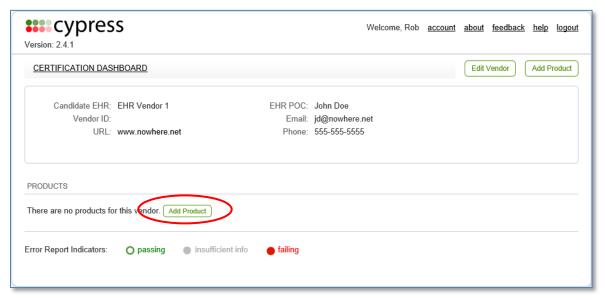


Figure 18: Vendor Certification Dashboard Product List

- On the EHR product form enter Product information (Product Name, Description and Version). Examples would be: product version number, the name and version of any optional modules installed in the product at the time of the test, and the operating system.
- Once the Product information is entered, select Create.

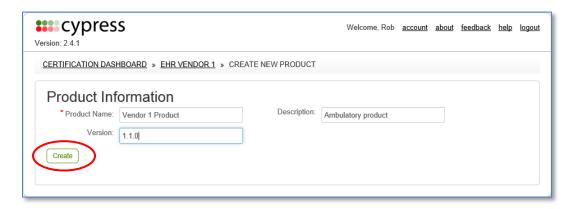


Figure 19: EHR Product form

- The Vendor, EHR Point of Contact and Product will now display on the Certification Dashboard.
- Select the product name under Passing Products to begin defining tests for the product.

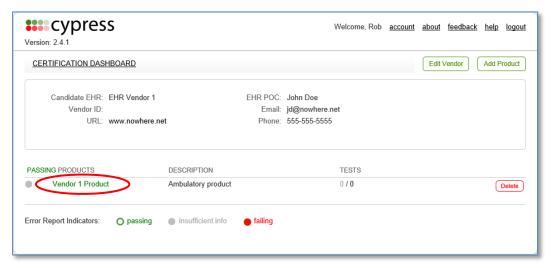


Figure 20: Certification Dashboard showing a vendor with one product added

Product Test Creation

- In order to test a product, it is necessary to define specific tests to execute.
- Select Add Test on the vendor product dashboard to begin creating a test for the product.

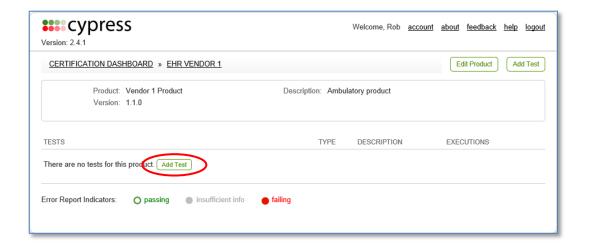


Figure 21: Dashboard showing Product and No Tests Added

 On the Create New Test Step 1 page, enter a Test Name, Brief Description and choose a Test Type. Then select Next.

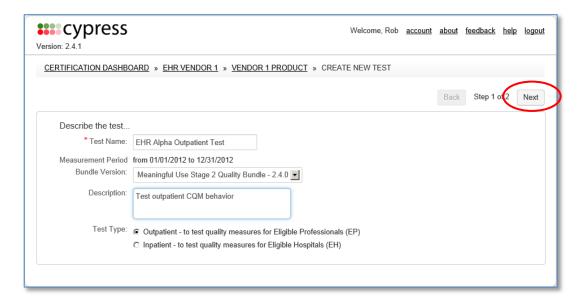


Figure 22: Create New Test - Step 1 Basic Information

• On the Create New Test Step 2 page, specify the measures that will be tested, then select Done to create the test.

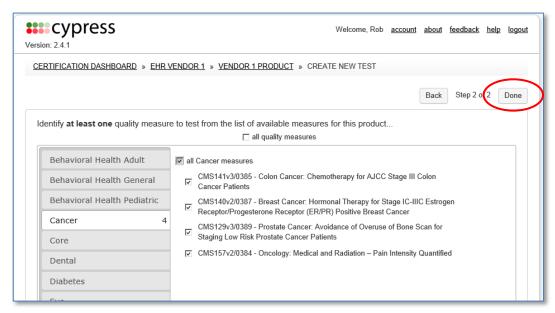


Figure 23: Create New Test - Step 2 CQM selection

• The test is now displayed on the Vendor Product Certification Dashboard.

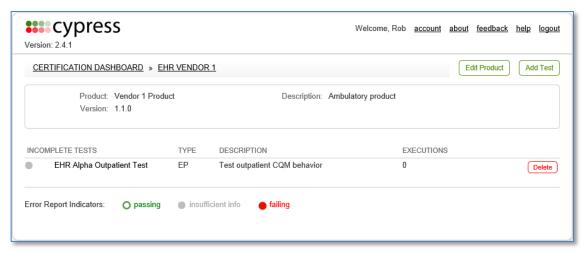


Figure 24: New Test Created

Test Execution

- This process evaluates the capability of the EHR system under test (SUT) to electronically generate the proper CQM artifacts for the CQMs being certified.
- The Test Proctor provides the Cypress v2.4 Test Data for the clinical quality measures for which the EHR system will be tested in the format selected to the EHR vendor via the Download Test Data.
- Depending on the test, the Vendor manually inputs or electronically downloads the patient test data into their EHR system.
 - Capture and Export: manual test data input (using html)
 - o Import and Calculate: QRDA Category 1 electronic input
- The Test Proctor examines the CQMs implemented in the EHR.

To begin testing, select the test name on the Vendor Product Certification Dashboard.
 This will display the product test page.

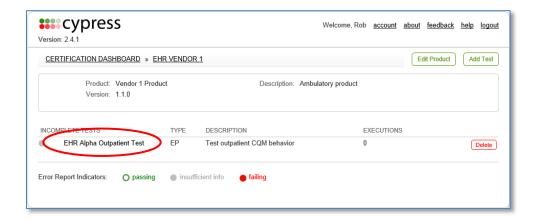


Figure 25: Select New Test

Download Patient Data

- Patient test data for the selected CQMs of the specified test must be downloaded in the format required for the test.
- Hover the mouse over the Test Data button below '1. Download Test Data' to display the download menu.
- Choose the format to download the data in (QRDA Cat 1, HTML) as required by the EHR. The downloaded patient record test data will be contained in a zip file (Figure 26).

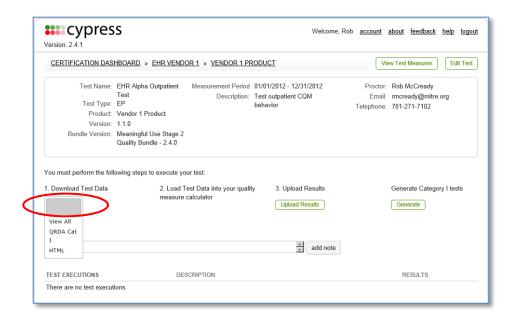


Figure 26: Download Patient Data for Import

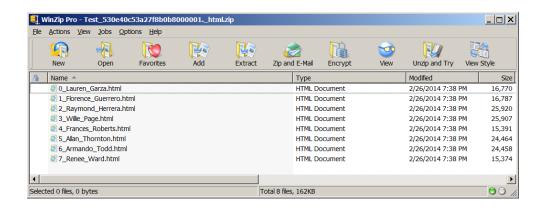


Figure 27: Listing of Zip file HTML Patient Test Data for CQMs to be tested

• Select a single patient record and open the HTML from the zip file listing to view it.

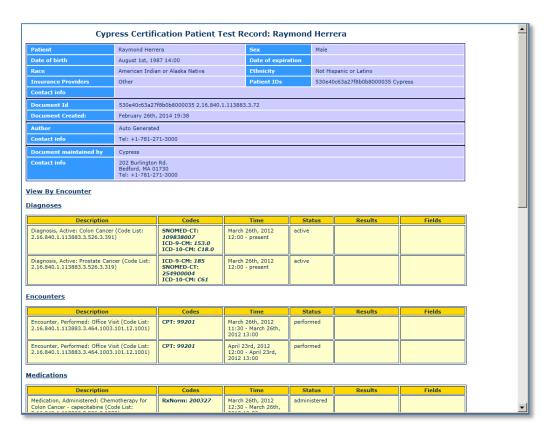


Figure 28: HTML for one Patient Record

Upload Results for Test

- Once Test Results in the QRDA Category III format have been generated by the EHR system, they are uploaded from the Certification Dashboard.
- Select Upload Results, browse to the QRDA Category III file to upload in the Results File dialog, and click Upload.

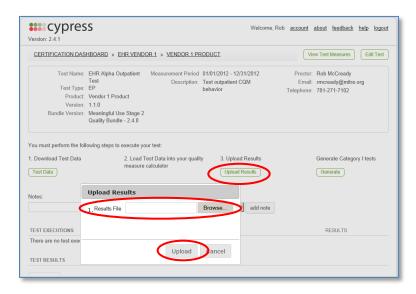


Figure 29: Upload test execution results

- The Test Proctor validates that the proper CQM artifacts in QRDA Category III file format for the test being performed are electronically generated by the EHR SUT.
- Validation results are displayed in the Certification Dashboard.
- Further detail of test results are available by selecting the various Test Results tabs.

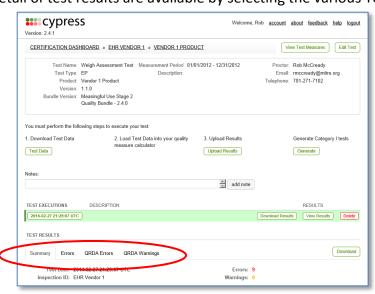


Figure 30: Test execution with validation errors

Category 1 Test

• Category 1 tests can be generated by selecting the Generate button under 'Generate Category 1 Tests' on the Certification Dashboard.

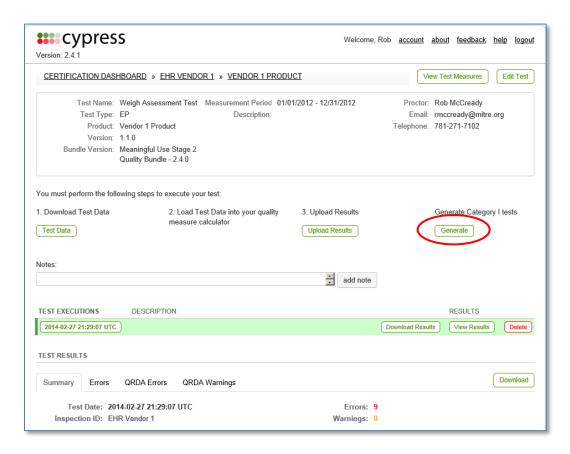


Figure 31: Details of test execution with errors

- The generated Category 1 test appears on the vendor product Certification Dashboard.
- Select the generated test to download test data and perform the test.

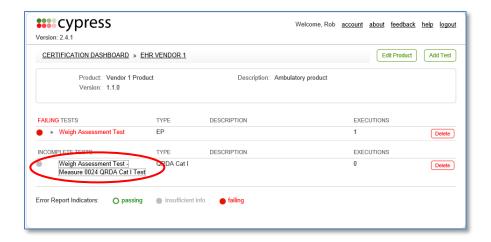


Figure 32: Generated Category 1 Test

- Hover the mouse over 'Test Data' below '1. Download Test Data' to display the test data download menu.
- Select the format to download the data in (QRDA Cat1, HTML) as required by the EHR system.

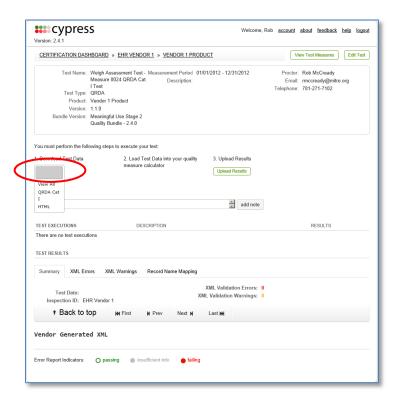


Figure 33: Download Data Cat 1 Test

- Just as with Category III testing, Category 1 results from the EHR system can be uploaded from the Certification Dashboard.
- Select 'Upload Results', choose the Category 1 results file, and select Upload.

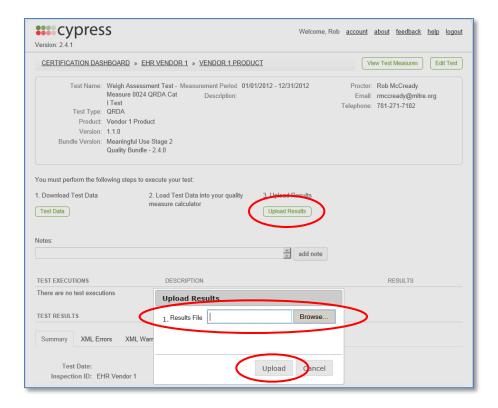


Figure 34: Upload Category 1 Results

• The Certification Dashboard displays the results of the Category 1 test.

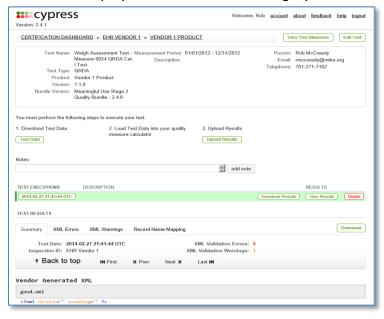


Figure 35: Category 1 Test Results

Test Execution Notes

The criteria used to determine a successful test outcome depends on whether the EHR product is being certified against the EP CQMs or the EH CQMs.

For EP CQMs, a successful test outcome is one in which the following conditions are true:

- 1. There were no XML validation errors in neither the QRDA Category I submitted data nor the QRDA Category III submitted data.
- 2. All of the CQM results calculated and submitted by the EHR SUT exactly match the values that Cypress v2.4 was expecting.

For EH CQMs, a successful test outcome is one in which the following conditions are true:

- 1. There were no XML validation errors in neither the QRDA Category I submitted data nor the QRDA Category III submitted data.
- 2. All of the CQM results calculated and submitted by the EHR SUT for discrete measures exactly match the values that Cypress v2.4 was expecting.
- 3. The CQM results calculated and submitted by the EHR SUT for continuous variable tests are within a defined delta of the value that Cypress v2.4 was expecting.

For both types of EHR technologies, it is acceptable for there to be XML validation *warnings* that are generated by Cypress' validation process. These warnings will not constitute a test failure. However, the Test Proctor should review the warnings generated and record any relevant observations that they can make about the reasons for the warnings in the **Notes** field on the Product Test details page.

Submit

Electronically submit generated CQM artifacts

Evaluates the capability to electronically submit a) calculated quality measures in accordance with the standard and implementation specifications; and b) exported patient data sufficient to allow external calculation.

- The Test Proctor commands the EHR SUT to generate and electronically submit the patient---level export in the QRDA Category I format for the clinical quality measures being tested.
- The Test Proctor commands the EHR SUT to generate and electronically submit an aggregate report in the QRDA Category III format of the clinical quality measures calculated in the Execute test.
- The Test Proctor validates that the calculated clinical quality measures are submitted in accordance with the QRDA Category III standard and implementation specifications by uploading the QRDA Category III XML via the Cypress v2.4 User Interface and the Cypress---supplied XML Schema validation.
- The Test Proctor validates that the exported patient---level CQM data are submitted in accordance with the QRDA Category I standard and implementation specifications by uploading the QRDA Category I XML via the Cypress v2.4 User Interface and the Cypress---supplied XML Schema validation.

Verify

Verify electronic and accurate generation of clinical quality measure artifacts

Evaluates the capability to electronically and accurately generate CQM artifacts appropriate for each phase of the test procedure.

- After the Test Proctor validates the submission of the QRDA Category III, the Test Proctor evaluates and displays the accuracy of the submitted clinical quality measure results via the Cypress v2.4 User Interface.
- The Test Proctor generates a test artifact bundle containing all test data used for this
 test execution, all products generated and submitted by the EHR SUT, and any other
 additional notes or information that the Test Proctor deems relevant into a single
 archive file that is cryptographically signed.

Acronyms

ATL Authorized Testing Lab

CMS Centers for Medicare & Medicaid Services

CQM Clinical Quality Measure

EH Eligible Hospital

EHR Electronic Health Record

EP Eligible Professional

HTML Hypertext Markup Language

NIST National Institute of Standards and Technology

ONC Office of the National Coordinator for Health Information Technology

QDM Quality Data Model

QRDA Quality Reporting Document Architecture

SUT System Under Test

XML Extensible Markup Language